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CANTOR COLBURN, LLP 55 GRIFFIN ROAD SOUTH BLOOMFIELD, CT 06002			HO, ALLEN C	
			ART UNIT	PAPER NUMBER
			2882	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/064,621

Applicant(s)

ACHARYA ET AL.

Examiner

Allen C. Ho

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 and 24-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 and 24-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

1. Claims 1, 20, and 27 are objected to because of the following informalities:

Claims 1, 20, and 27 recite "said first set of image data includes hard tissue and soft tissue calcified plaque data" and "said third set of image data contains soft calcified plaque data". However, applicant's specification disclosed that soft non-calcified plaques are more dangerous than hard calcified plaques because they are more likely to detach and cause blood clot (paragraphs [0005] and [0027]). It would seem that the applicants' invention is designed to detect soft non-calcified plaques. Accordingly, the claims should be amended to recite "soft tissue non-calcified plaque" and "hard tissue calcified plaque".

Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 20-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Ogawa *et al.* U. S. Patent No. 6,278,760 B1).

With regard to claim 20, Ogawa *et al.* disclosed a system, comprising: an imaging system generating a first set of image data and a second set of image data responsive to an object, the generating of the first set of image data in response to a first x-ray energy level (column 6, lines 35-39) and generating of the second set of image data in response to a second x-ray energy level (column 6, lines 39-45), each set of image data includes a plurality of pixel elements (a two-dimensional solid state detector of a cone-beam CT has plurality of pixels); and a processing device (20) in communication with the imaging system obtaining the first set of image data and the second set of image data from the imaging system, and calculating a third set of image data by subtracting (21) each of the second pixel element from the corresponding first pixel element. The contents of the image data are not accorded any patentable weight. MPEP § 2114 and § 2115.

With regard to claim 21, Ogawa *et al.* disclosed the system of claim 20, wherein the object is a patient (identifying a diseased part).

With regard to claim 22, Ogawa *et al.* disclosed the system of claim 20, wherein the imaging system is a computed tomography imaging system (column 6, lines 6-13).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. Claims 1 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogawa *et al.* (U. S. Patent No. 6,278,760 B1) in view of Tsutshi *et al.* (U. S. Patent No. 5,396,530) and Merickel *et al.* (U. S. Patent No. 4,945,478).

With regard to claim 1, Ogawa *et al.* disclosed a method comprising: obtaining a first set of image data created in response to a first x-ray energy level (column 6, lines 35-39) and including a plurality of first pixel elements (a two-dimensional solid state detector of a cone-beam CT has a plurality of pixel elements), wherein each of the first pixel elements corresponds to a unique location in an object being scanned and the first set of image data includes hard tissue and soft tissue calcified plaque data (if the object has hard tissue and soft tissue calcified plaque); obtaining a second set of image data created in response to a second x-ray energy level (column 6, lines 39-45) and including a plurality of second pixel elements, wherein each of the second pixel elements corresponds to one of the first pixel elements and wherein the second x-ray energy level is higher than the first x-ray energy level and the second set of image data contains the hard tissue calcified plaque data (if the object has hard tissue calcified plaque); and calculating (20) a third set of image data in response to the first set of image data and the second set of image data, wherein the calculating includes subtracting (21) each of the second pixel elements from the corresponding first pixel element and the third set of image data contains the soft tissue calcified plaque data (if the object has soft tissue calcified plaque).

However, Ogawa *et al.* failed to teach that this method is used for plaque characterization.

Tsutshi *et al.* taught that the method of energy subtraction can be used to separate materials of different composition such as a bone, a soft tissue, a blood vessel, or a calcified tissue (column 4, lines 56-63).

Furthermore, Merickel *et al.* taught that any diagnosis or evaluation of the physiological stage of the atherosclerosis would necessarily involve identification and characterization of the plaque (column 4, lines 16-27).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use the method disclosed by Ogawa *et al.* for plaque characterization, since a person would be motivated to diagnose atherosclerosis using a noninvasive method that poses a least amount of risk to a patient.

With regard to claim 5, Ogawa *et al.* in combination with Tsutshi *et al.* and Merickel *et al.* disclosed the method of claim 1, wherein the object is a patient (column 7, lines 40-42).

6. Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogawa *et al.* (U. S. Patent No. 6,278,760 B1), Tsutshi *et al.* (U. S. Patent No. 5,396,530), and Merickel *et al.* (U. S. Patent No. 4,945,478) as applied to claim 1 above, and further in view of Gordon *et al.* (U. S. Patent No. 5,661,774).

With regard to claims 2-4, Ogawa *et al.* in combination with Tsutshi *et al.* and Merickel *et al.* disclosed the method of claim 1.

However, Ogawa *et al.*, Tsutshi *et al.*, and Merickel *et al.* failed to teach or fairly suggest that each of the second pixel elements and each of the corresponding first pixel elements are created in less than one millisecond from each other within the same scan in an interleaving pattern.

Gordon *et al.* disclosed a dual-energy power supply that is capable of switching between a high-energy x-ray level and a low-energy x-ray level at a high modulation frequency up to 800 Hz, *i. e.*, the high-energy x-ray pulses and the low-energy x-ray pulses are separated by 0.625 ms (column 7, lines 12-32); the high-energy pixels and the low-energy pixels are acquired less than one millisecond from each other.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the dual-energy power supply disclosed by Gordon *et al.* with a dual-energy cone-beam CT scanner, since a person would be motivated to acquire a high-energy image and a low-energy image as close to each other on the time scale as possible so that a clear subtraction image can be formed. In imaging a dynamic (time-dependent) object, a blurred subtraction image would result if the high-energy image and the low-energy image were sufficiently far apart on the time scale that they capture different motion states of the object.

7. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogawa *et al.* (U. S. Patent No. 6,278,760 B1), Tsutshi *et al.* (U. S. Patent No. 5,396,530), and Merickel *et al.* (U. S. Patent No. 4,945,478) as applied to claim 1 above.

With regard to claims 6 and 7, Ogawa *et al.* in combination with Tsutshi *et al.* and Merickel *et al.* disclosed the method of claim 1.

Although Ogawa *et al.* taught that the first x-ray energy level is 60 kV and the second x-ray energy level is 120 kV, they failed to teach or fairly suggest that the first x-ray energy level is 80 kV and the second x-ray energy level is 140 kV.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to use 80 kV and 140 kV as the first x-ray energy level and the second x-ray

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energy level, respectively, since a person skilled in the art would recognize that this method would work for any two different x-ray energy levels.

8. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ogawa *et al.* (U. S. Patent No. 6,278,760 B1), Tsutshi *et al.* (U. S. Patent No. 5,396,530), and Merickel *et al.* (U. S. Patent No. 4,945,478) as applied to claim 1 above, and further in view of Brown (U. S. Patent No. 5,459,769).

With regard to claim 8, Ogawa *et al.* in combination with Tsutshi *et al.* and Merickel *et al.* disclosed the method of claim 1.

However, Ogawa *et al.*, Tsutshi *et al.*, and Merickel *et al.* failed to teach or fairly suggest that the object being scanned was injected with a contrast agent.

Brown disclosed a method for monitoring a patient injected with a contrast agent.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to inject the object with a contrast agent, since a person would be motivated to distinguish the region of interest from surrounding tissues with a contrast agent so that the region of interest could be clearly identified.

9. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ogawa *et al.* (U. S. Patent No. 6,278,760 B1), Tsutshi *et al.* (U. S. Patent No. 5,396,530), and Merickel *et al.* (U. S. Patent No. 4,945,478) as applied to claim 1 above.

With regard to claim 9, Ogawa *et al.* in combination with Tsutshi *et al.* and Merickel *et al.* disclosed the method of claim 1.

However, Ogawa *et al.*, Tsutshi *et al.*, and Merickel *et al.* failed to teach or fairly suggest displaying the first set of image data, the second set of image data, and the third set of image data.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to display all image data, since a person would be motivated to review all the images to obtain an understanding of the situation.

10. Claims 10, 12, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogawa *et al.* (U. S. Patent No. 6,278,760 B1), Tsutshi *et al.* (U. S. Patent No. 5,396,530), and Merickel *et al.* (U. S. Patent No. 4,945,478) as applied to claim 1 above, and further in view of Keyes *et al.* (U. S. Patent No. 4,559,557).

With regard to claims 10, 12, and 14, Ogawa *et al.* in combination with Tsutshi *et al.* and Merickel *et al.* disclosed the method of claim 1, wherein the first set of image data, the second set of image data, and the third set of image data were created as non-contrast images.

However, Ogawa *et al.*, Tsutshi *et al.*, and Merickel *et al.* failed to teach or fairly suggest the method further comprising the steps of: obtaining a fourth set of image data created in response to the first x-ray energy level, wherein the fourth set of image data was created as a contrast image; obtaining a fifth set of image data created in response to the second x-ray energy level, wherein the fifth set of image data was created as a contrast image; calculating a sixth set of image data in response to the fourth set of image data and the fifth set of image data, wherein calculating the sixth set of image data includes subtracting the fifth set of image data from the fourth set of image data; calculating a seventh set of image data in response to the first set of image data and the fourth set of image data, wherein calculating the seventh set of image data

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includes subtracting the first set of image data from the fourth set of image data; calculating an eighth set of image data in response to the second set of image data and the fifth set of image data, wherein calculating the seventh set of image data includes subtracting the second set of image data from the fifth set of image data; and calculating a ninth set of image data in response to the third set of image data and the sixth set of image data, wherein calculating the ninth set of image data includes subtracting the third set of image data from the sixth set of image data.

Keyes *et al.* disclosed a method of hybrid subtraction for dual-energy x-ray, comprising the steps of: obtaining contrast images at low-energy (fourth set of image data) and high energy (fifth set of image data), and calculating a subtraction contrast image (sixth set of image data) in response to those contrast images (column 2, lines 62-68; column 3, lines 1-3); calculating subtraction images (seventh, eighth, and ninth) by subtracting non-contrast images (first, second, and third) from contrast images (fourth, fifth, and sixth) (column 3, lines 3-8). Keyes *et al.* taught that a major advantage of the hybrid subtraction technique is that it suppresses artifacts due to motions of the soft tissues (column 3, lines 8-12).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to form hybrid subtractions, since a person would be motivated to obtain an image that clearly identifies the arteries that contain contrast medium without any artifacts due to motions of the soft tissues.

With regard to claims 11, 13, and 15, Ogawa *et al.*, Tsutshi *et al.*, and Merickel *et al.* in combination with Keyes *et al.* disclosed the method of claims 10, 12, and 14.

However, Ogawa *et al.*, Tsutshi *et al.*, Merickel *et al.*, and Keyes *et al.* failed to teach or fairly suggest displaying the fourth set of image data, the fifth set of image data, the sixth set of

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image data, the seventh set of image data, the eighth set of image data, and the ninth set of image data.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to display all image data, since a person would be motivated to review all the images to obtain an understanding of the situation.

11. Claims 16 and 18 rejected under 35 U.S.C. 103(a) as being unpatentable over Ogawa *et al.* (U. S. Patent No. 6,278,760 B1), Tsutshi *et al.* (U. S. Patent No. 5,396,530), and Merickel *et al.* (U. S. Patent No. 4,945,478) as applied to claims 1 above, and further in view of Brown (U. S. Patent No. 5,459,769).

With regard to claim 16, Ogawa *et al.* in combination with Tsutshi *et al.* and Merickel *et al.* disclosed the method of claim 1.

However, Ogawa *et al.*, Tsutshi *et al.*, and Merickel *et al.* failed to teach or fairly suggest the method further comprising the steps of: locating a vessel of interest in the object, wherein the object was injected with a contrast agent; tracking a flow of the contrast agent through the vessel; and quantifying plaque in the vessel in response to the third set of image data and to the flow.

Brown disclosed a method comprising the steps of: locating a vessel (106, 108) of interest in the object (column 4, lines 18-21), wherein the object was injected with a contrast agent (116); tracking (monitoring) a flow of the contrast agent through the vessel (120).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to perform the method steps disclosed by Brown, since a person would be motivated to acquire contrast images when the contrast agent has reached the vessel of interest.

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Furthermore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to quantify plaque in the vessel in response to the third set of image data and to the flow, since a person would be motivated to perform data reduction to arrive at figures that would characterize the plaque so that the figures could be monitored and compared with future measurements in a consistent fashion.

With regard to claim 17, Ogawa *et al.* in combination with Tsutshi *et al.*, Merickel *et al.*, and Brown disclosed the method of claim 16.

However, Ogawa *et al.*, Tsutshi *et al.*, Merickel *et al.*, and Brown failed to teach or fairly suggest that tracking is performed in response to the second set of image data.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to track the flow of the contrast agent in response to the second set of image data, since a person would be motivated to track the contrast agent using either low-energy or high-energy x-rays depending on the x-ray absorption characteristics of the contrast agent.

12. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Macovski (U. S. Patent No. 4,686,695) in view of Merickel *et al.* (U. S. Patent No. 4,945,478).

With regard to claim 19, Macovski disclosed a method comprising: obtaining image data created in response to first and second x-ray energy levels (V_1 and V_2) and an object injected with a contrast agent; locating a vessel of interest (27) in the object (10); tracking a flow of the contrast agent through the vessel (inherent).

However, Macovski failed to teach the steps of identifying soft plaque in the vessel in response to the image data and to the flow; plotting the distribution of the soft plaque; and determining the vulnerability of the soft plaque in response to the distribution.

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Merickel *et al.* taught that any diagnosis or evaluation of the physiological stage of the atherosclerosis would necessarily involve identification and characterization of the soft plaque (column 4, lines 16-27).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to identify soft plaque in the vessel, since a person would be motivated to evaluate the physiological stage of the atherosclerosis so that a diagnosis could be rendered.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to plot the distribution of the soft plaque, since a person would be motivated to determine the affected area and the extend of the problem.

Furthermore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to determine the vulnerability of the soft plaque in response to the distribution, since a person would be motivated to assign a risk factor in the diagnosis.

13. Claims 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogawa *et al.* (U. S. Patent No. 6,278,760 B1) as applied to claim 20 above, further in view of Kita (U. S. Patent No. 6,438,200 B1).

With regard to claims 24-26, Ogawa *et al.* disclosed the system of claim 20. However, Ogawa *et al.* failed to teach that the processing device is remotely located from the imaging system, in communication with the imaging device over the Internet.

Kita disclosed remote processing devices (4, 5) in communication with the imaging device (1) over the Internet (column 3, lines 7-30).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to connect the processing device remotely from the imaging system using

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the Internet, since a person would be motivated to send the data to another location for consultation or storage.

14. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ogawa *et al.* (U. S. Patent No. 6,278,760 B1), Tsutshi *et al.* (U. S. Patent No. 5,396,530), and Merickel *et al.* (U. S. Patent No. 4,945,478) as applied to claim 1 above, and further in view of Takasawa (U. S. Patent No. 6,501,827 B1).

With regard to claim 27, Ogawa *et al.* in combination with Tsutshi *et al.* and Merickel *et al.* disclosed the method of claim 1.

However, Ogawa *et al.*, Tsutshi *et al.*, and Merickel *et al.* failed to teach or fairly suggest a computer program product for plaque characterization in cardiac applications, the product comprising: a storage medium readable by a processing circuit and storing instructions for execution by the processing circuit comprising the steps as claimed in claim 1.

Takasawa taught storing instructions on a storage medium readable and executable by a processing circuit (column 5, lines 25-33).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to provide a storage medium storing instructions comprising the method steps, since a person would be motivated to program a processing circuit (controller) of an x-ray imaging system to perform the method steps.

15. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ogawa *et al.* (U. S. Patent No. 6,278,760 B1), Tsutshi *et al.* (U. S. Patent No. 5,396,530), Merickel *et al.* (U. S. Patent No. 4,945,478), and Takasawa (U. S. Patent No. 6,501,827 B1) as applied to claim 27 above, and further in view of Gordon *et al.* (U. S. Patent No. 5,661,774).

With regard to claim 28, Ogawa *et al.*, Tsutshi *et al.*, Merickel *et al.*, Takasawa, and Gordon *et al.* disclosed the computer program product of claim 27.

However, Ogawa *et al.*, Tsutshi *et al.*, Merickel *et al.*, Takasawa, and Gordon *et al.* failed to teach or fairly suggest that each of the second pixel elements and the corresponding first pixel elements are created with the same scan in an interleaving pattern.

Gordon *et al.* disclosed a dual-energy power supply that is capable of switching between a high-energy x-ray level and a low-energy x-ray level at a high modulation frequency up to 800 Hz, *i. e.*, the high-energy x-ray pulses and the low-energy x-ray pulses are separated by 0.625 ms (column 7, lines 12-32); the high-energy pixels and the low-energy pixels are acquired less than one millisecond from each other.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ the dual-energy power supply disclosed by Gordon *et al.* with a dual-energy cone-beam CT scanner, since a person would be motivated to acquire a high-energy image and a low-energy image as close to each other as possible so that a clear subtraction image can be formed. In imaging a dynamic (time-dependent) object, a blurred subtraction image would result if the high-energy image and the low-energy image were far apart on the time scale that they capture different motion states of the object.

16. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Macovski (U. S. Patent No. 4,686,695) in view of Merickel *et al.* (U. S. Patent No. 4,945,478) as applied to claim 19 above, and further in view of Takasawa (U. S. Patent No. 6,501,827 B1).

With regard to claim 29, Macovski in combination with Merickel *et al.* disclosed the method for plaque characterization of claim 19.

However, Macovski and Merickel *et al.* failed to teach or fairly suggest a computer program product for plaque characterization in cardiac applications, the product comprising: a storage medium readable by a processing circuit and storing instructions for execution by the processing circuit comprising the steps as claimed in claim 19.

Takasawa taught storing instructions on a storage medium readable and executable by a processing circuit (column 5, lines 25-33).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to provide a storage medium storing instructions comprising the method steps, since a person would be motivated to program a processing circuit (control unit) of an x-ray imaging system to perform the method steps.

Response to Arguments

17. Applicant's arguments filed 22 December 2003 have been fully considered but they are not persuasive.

With regard to claim 1, the examiner takes the position that the image data would necessarily "include hard tissue and soft tissue calcified plaque data" if the patient has hard tissue and soft tissue calcified plaques. Furthermore, the teaching of Merickel *et al.* was only relied upon to teach the different types of plaques, and that the soft tissue types of plaques could be utilized to evaluate the physiological stage of the disease.

18. Applicant's arguments with respect to claims 19-22, 24-26, and 29 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- (1) Besch *et al.* (U. S. Patent No. 6,356,617 B1) disclosed a device for digital subtraction angiography.
- (2) Ohtsuchi *et al.* (U. S. Patent No. 5,247,559) disclosed a substance quantitative analysis method.
- (3) Picard *et al.* (U. S. Patent No. 5,123,037) disclosed method for calibrating the measuring system of an x-ray apparatus.
- (4) Graeff *et al.* (U. S. Patent No. 4,736,398) disclosed an apparatus for digital subtraction angiography in energy subtraction mode.
- (5) Alvarez *et al.* (U. S. Patent No. 4,029,963) disclosed an x-ray spectral decomposition imaging system.

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allen C. Ho whose telephone number is (571) 272-2491. The examiner can normally be reached on Monday - Friday from 8:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Edward J. Glick can be reached at (571) 272-2490. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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